K100232

SECTION 5- 510(k) SUMMARY

MAY 21 2010

Submission Correspondent:	Talladium Inc.
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Establishment Registration No	2023129
Date Prepared:	January 12, 2010
Trade Name :	Luminesse Zirconia
Common/Usual Name:	Porcelain Powder Blanks for Dental Restorations
Classification Name:	Porcelain Powder for Clinical Use
Classification Number:	872.6660
Classification Panel:	Dental Devices
CDRH Product Code:	EIH
Regulatory Class:	**II**
Predicate Devices:	1. LAVA FRAME by 3M ESPE (K011394) 2. Avante Z Zirconia by Pentron Ceramics (K081749) 3. IPS e.max ZirCAD by Ivoclar Vivadent AG (K051705) 4. Cercon Base by Degussa Dental (K013230)
Device Description:	Luminesse Zirconia blanks, are high purity, bisque fired zirconia machining blanks. The powders pressed to form these blanks are of a uniform size and well dispersed, ensuring no agglomerates. The resultant fine grained, bisque body allows intricate shapes to be machined with tight tolerances. Luminesse Zirconia blanks are phase

stabilized with 3 mol % yttria and therefore do not undergo the usual phase transitions associated with pure zirconia. This phase transformation "toughens" the zirconia and stops crack propagation, yielding high fracture toughness and high strength. The highest purity powders are used to make Luminesse Zirconia Blanks minimizing trace oxides. Luminesse Blanks are 99.9 wt% $ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3$. The natural zirconia minerals HfO_2, which is so similar in structure and chemical properties to zirconia, that it has no effect on product properties. A small addition of alumina minimizes hydrothermal aging.

Luminesse Zirconia Blanks are dental ceramic blanks designed for the manufacturing of substructures for ceramic dental appliances. The dental appliance is machined either by CAD/CAM machining or using the copying technique. All appliances are for the sole use of the particular patient only. A metal chuck is glued on the end of blank or a metal ring that holds it in the CAD/CAM machine which is used to machine the final dental restoration. After completion of the machining steps, the dental restoration is fired (i.e., sintered) in the oven to harden the ZrO_2.

Intended Use:

Luminesse ZR Blanks are intended for CAD/CAM fabrication of all-ceramic (no metal) dental restorations. Luminesse ZR Blanks are partially sintered Yttria stabilized zirconia blanks for use as CAD/CAM milling blanks. They are isostatically cold pressed so they can be milled using any compatible CAD/CAM machine such as Sirona InLab by Sirona Dental Systems, LLC, Charlotte, NC or KaVO Everest by KaVo Dental, Lake Zurich, IL.

After the ZR Blank is milled, it is sintered, causing the materials to densify into a high strength ceramic material which is suitable for dental inlays, onlays, crowns and bridges.

Safety and Effectiveness:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics. But, it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

As such, it has been shown in this 510(k) submission, that the differences between the Luminesse Zirconia blanks and the predicate devices do not raise any questions regarding their safety and effectiveness. The Luminesse Zirconia blanks as designed and manufactured are as safe and effective as the predicate device and therefore are determined to be substantially equivalent to the referenced predicate device.

Technological Characteristics:

The tests methods Flexural Strength and Chemical solubility were used on IPS e.max ZirCAD by Ivoclar (K051705). These test methods were followed by the International Standards Organization (6872).

Performance Criteria:

IPS e.max ZirCAD by Ivoclar (K051705) used the Biaxial Strength method to test Flexural Strength (ISO 6872). Chemical Solubility for mass loss was also tested according to ISO 6872 using the method of a 4% solution acetic acid.

Since the predicate and proposed devices are exactly identical in formulation, there is no need for further testing. They are made from the same materials and have the same intended use.

Device Name:

Luminesse Zirconia Blanks

Sizes:

Blocks	Discs
14mm x 13mm x 15mm	10mm x 98.5mm
20mm x 15mm x 15mm	14mm x 98.5mm
20mm x 19mm x 15rm	16mm x 98.5mm
40mm x 15mm x 15mm	18mm x 98.5mm
40mm x 19mm x 15mm	20mm x 98.5mm
55mm x 19mm x 15mm	25mm x 98.5mm
65mm x 25mm x 15mm	10mm x 100mm
85mm x 25mm x15mm	12mm x 100mm
25mm x 57mm x 15mm	14mm x 100mm
42mm x 20mm x 16mm	16mm x 100mm
42mm x 20mm x 20mm	18mm x 100mm
60mm x 20mm x 25mm	20mm x 100mm
43mm x 25mm x 16mm	25mm x 100mm
58mm x 29mm x 16mm	
72mm x 42mm x 16mm	
87mm x 56mm x 16mm	

Cylinders

16mm x 16mm
20mm x 20 mm

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The 510K "Substantial Equivalence" Decision Making Process was followed as described herein.

1. The Luminesse ZR Blanks have the *same intended use,* to be luted/cemented into place as inlays, onlays, veneers or crowns and for use as bridge components to repair damaged teeth.
2. The *technological characteristics* of the Luminesse ZR Blanks are similar to those for predicate devices and those currently on the market. In addition, the technological differences if any are well understood in the Dental Industry. The use of computerized lathe systems to prepare the inlay or onlay in the Dental Office, also has been cleared by 510(k) . Reference: K950299, K972276, etc..
3. The material which make up the Luminesse ZR Blanks are well established in more demanding areas such as zirconia abutments anchored to a titanium surgical implant.
4. The FDA "Decision Making Process" chart was used for this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 21 2010

Mr. Edward Harms
Vice President QA/RA
Talladium, Incorporated
27360 West Muirfield Lane
Valencia, California 91355

Re: K100232
Trade/Device Name: Luminesse ZR Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 12, 2010
Received: May 14, 2010

Dear Mr. Harms:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K100232

Device Name: Luminesse ZR Blanks

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kim Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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